NDA 19-190/S-036

Wyeth Ayerst Research
Attention: Jennifer Phillips, Pharm.D.
Director, Women's Health Care Products
US Regulatory Affairs
P.O. Box 8299

MAR 23 2000

Philadelphia, PA 19101-8299 Dear Dr. Phillips:

Please refer to your supplemental new drug application dated September 13, 1999, received September *15,* 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Triphasil® 28 Tablets (levonorgestrel/ethinyl estradiol).

We acknowledge receipt of your submission dated November 30, 1999.

This supplemental new drug application provides for changes to the **INDICATIONS AND USAGE, PRECAUTIONS,** and **HOW SUPPLIED** sections of the label. The changes are as follows:

INDICATIONS AND USAGE section

The Trussel Table has been updated to the 1998 table and include the results of the contraceptive sponge and female condom.

PRECAUTIONS section

A Pediatric Use subsection has been added that reads:

> "Safety and efficacy of [Tradename] has been established in women of reproductive age. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and users 16 and older. Use of this product before menarche is not indicated."

HOW SUPPLIED section:

This section has been revised to specify that the product will now be available in 50 pilpak dispensers for the clinic pilpak packaging.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package

insert).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-190/S-036." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mockup form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D., M.P.H.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research